



IPW 1615

PATENT

Attorney Docket No. CUTLER-06830

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Neal R. Cutler

Serial No.: 10/091,847

Group No.: 1615

Filed: 03/06/02

Examiner:

Entitled: **Sublingual Administration of Dihydroergotamine For
The Treatment Of Migraine**

**INFORMATION DISCLOSURE
STATEMENT TRANSMITTAL**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: December 22, 2004

By: Kelly J. Collins

Kelly J. Collins

Sir or Madam:

Enclosed please find an Information Disclosure Statement and Form PTO-1449, including copies of the references contained thereon, for filing in the U.S. Patent and Trademark Office.

A check for \$180.00 is also enclosed pursuant to 37 C.F.R. § 1.17(p) for filing this Information Disclosure Statement after three months as set forth in 37 C.F.R. § 1.97(c).

The Commissioner is hereby authorized to charge any additional fee or credit overpayment to our Deposit Account No. **08-1290**. **An originally executed duplicate of this transmittal is enclosed for this purpose.**

Dated: December 22, 2004

Thomas W. Brown

Registration No. 50,002

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San Francisco, California 94105
617/984.0616



PATENT

Attorney Docket No. CUTLER-06830

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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INFORMATION DISCLOSURE STATEMENT

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Dated: <u>December 22, 2004</u>	By: <u></u> Kelly J. Collins

Sir:

The citations listed below, copies attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application.

The following printed publications are referred to in the body of the specification:

- U.S. Pat. No. 4,389,393 to Schor *et al.*;
- U.S. Pat. No. 4,650,810 to Bays *et al.*;
- U.S. Pat. No. 4,914,125 to Baldinger *et al.*;
- U.S. Pat. No. 4,916,125 to Herrling *et al.*;
- U.S. Pat. No. 4,933,367 to Wolff *et al.*;
- U.S. Pat. No. 4,963,367 to Ecanow;
- U.S. Pat. No. 4,994,483 to Oxford *et al.*;
- U.S. Pat. No. 5,006,342 to Cleary *et al.*


- U.S. Pat. No. 5,021,428 to Carr *et al.*;
- U.S. Pat. No. 5,051,426 to Parnell;
- U.S. Pat. No. 5,200,413 to King *et al.*;
- U.S. Pat. No. 5,242,949 Goldberg *et al.*;
- U.S. Pat. No. 5,248,684 to Suzuki *et al.*;
- U.S. Pat. No. 5,273,759 to Simmons;
- U.S. Pat. No. 5,288,498 to Stanley *et al.*;
- U.S. Pat. No. 5,317,103 to Baker *et al.*;
- U.S. Pat. No. 5,364,863 to Cohen *et al.*;
- U.S. Pat. No. 5,399,574 to Robertson *et al.*;
- U.S. Pat. No. 5,434,154 to Smith *et al.*;
- U.S. Pat. No. 5,441,969 to Axelsson *et al.*;
- U.S. Pat. No. 5,464,864 to King *et al.*;
- U.S. Pat. No. 5,466,699 to Robertson *et al.*;
- U.S. Pat. No. 5,468,768 to Cipollina *et al.*;
- U.S. Pat. No. 5,487,898 to Lu *et al.*;
- U.S. Pat. No. 5,491,148 to Berger *et al.*;
- U.S. Pat. No. 5,494,910 to North *et al.*;
- U.S. Pat. No. 5,624,687 to Yana *et al.*;
- U.S. Pat. No. 5,637,611 to King *et al.*;
- U.S. Pat. No. 5,672,356 to Rault *et al.*;
- U.S. Pat. No. 5,855,907 to Peyman;
- U.S. Pat. No. 5,872,145 to Placetka;
- U.S. Pat. No. 5,877,183 to Cincotta;
- U.S. Pat. No. 5,981,885 to Caruso;
- U.S. Pat. No. 5,939,425 to Caruso;
- U.S. Pat. No. 5,942,251 to Merkus;
- U.S. Pat. No. 5,955,502 to Hansen *et al.*;
- U.S. Pat. No. 6,010,719 to Remon *et al.*;
- U.S. Pat. No. 6,043,244 to Caruso;
- U.S. Pat. No. 6,077,539 to Plachetka *et al.*;

- U.S. Pat. No. 6,103,218 to Brucker *et al.*;
- U.S. Pat. No. 6,139,819 to Unger *et al.*;
- U.S. Pat. No. 6,197,331 to Lerner *et al.*;
- U.S. Pat. No. 6,200,604 to Pather *et al.*;
- U.S. Pat. No. 6,221,392 to Khankari *et al.*;
- WO Pat. No. 00/16750 to Pettersson *et al.*;
- EPO Pat. No. 0 324 725 B1 to Nystrom *et al.*;
- Goodman and Gilman's "The Pharmaceutical Basis of Therapeutics", 8th ed., McGraw-Hill, Inc. (1990), pp. 944-947;
- Becker, "Migraine-associated symptoms: Clinical significance and management," *Can J Clin Pharmacol* 6 (Suppl A):15A-19A (1999);
- Kiechel, "The Bioavailability and Kinetics of Dihydroergotamine" in Fitacha (Ed.); *Neuester Scand Der Dihydergot Forschung*. Sturtgart Georg Thiema: 32-46 (1984);
- Migranal (dihydroergotamine mesylate, USP) Nasal Spray Information, Novartis Pharmaceuticals Company, Inc. Publication 30721901, 1997;
- D.H.E. 45 (dihydroergotamine mesylate) Injection, USP Information, Novartis Pharmaceuticals Company, Inc., Publication 30220906, 1998; and
- Pharmaceutical Dosage Form: Tablets Vol. 1, 2nd Edition, Lieberman H. A. *et al.*, Eds. Marcel Dekker, New York and Basel 1989. p. 354-356.

This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Respectfully submitted,

Dated: December 22, 2004



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Registration No. 50,002

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FORM PTO-1449
(Modified)U.S. Department of Commerce
Patent and Trademark Office

Attorney Docket No.: CUTLER-06830

Serial No.: 10/091,847

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Use Several Sheets If Necessary)

Applicant: Neal R. Cutler

Filing Date: 03/06/02

Group Art Unit: 3613

(37 CFR § 1.98(b))

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Serial / Patent Number	Issue Date	Applicant / Patentee	Class	Subclass	Filing Date
	1	4,389,393	6/21/83	Schor <i>et al.</i>	424	19	3/26/82
	2	4,650,810	3/17/87	Bays <i>et al.</i>	514	415	1/26/83
	3	4,914,125	4/03/90	Baldinger <i>et al.</i>	514	520	7/06/89
	4	4,916,125	4/10/90	Herrling <i>et al.</i>	514	89	7/11/89
	5	4,933,367	6/12/90	Wolff <i>et al.</i>	514	570	7/10/86
	6	4,963,367	10/16/90	Ecanow	424	485	12/15/87
	7	4,994,483	2/19/91	Oxford <i>et al.</i>	514	415	11/30/89
	8	5,006,342	4/09/91	Cleary <i>et al.</i>	424	445	2/10/89
	9	5,021,428	6/04/91	Carr <i>et al.</i>	514	317	11/17/89
	10	5,051,426	9/24/91	Parnell	514	263	3/27/90
	11	5,200,413	4/06/93	King <i>et al.</i>	514	299	8/05/91
	12	5,242,949	9/07/93	Goldberg <i>et al.</i>	514	652	3/13/92
	13	5,248,684	9/28/93	Suzuki <i>et al.</i>	514	299	5/21/91
	14	5,273,759	12/28/93	Simmons	424	465	9/17/92
	15	5,288,498	2/22/94	Stanley <i>et al.</i>	424	440	9/05/89
	16	5,317,103	5/31/94	Baker <i>et al.</i>	544	367	7/16/92
	17	5,364,863	11/15/94	Cohen <i>et al.</i>	514	304	4/26/93
	18	5,399,574	3/21/95	Robertson <i>et al.</i>	514	339	6/06/91
	19	5,434,154	7/18/95	Smith <i>et al.</i>	514	249	4/26/94
	20	5,441,969	8/15/95	Axelsson <i>et al.</i>	514	338	12/22/93
	21	5,464,864	11/07/95	King <i>et al.</i>	514	468	6/17/92
	22	5,466,699	11/14/95	Robertson <i>et al.</i>	514	323	12/05/94
	23	5,468,768	11/21/95	Cipollina <i>et al.</i>	514	415	1/06/94
	24	5,487,898	1/30/96	Lu <i>et al.</i>	424	435	2/07/94
	25	5,491,148	2/13/96	Berger <i>et al.</i>	514	305	4/26/91
	26	5,494,910	2/27/96	North <i>et al.</i>	514	233.5	10/14/93
	27	5,624,687	4/29/97	Yano <i>et al.</i>	424	490	4/14/92
	28	5,637,611	6/10/97	King <i>et al.</i>	514	468	5/15/95
	29	5,672,356	9/30/97	Rault <i>et al.</i>	424	468	9/21/94
	30	5,855,907	1/05/99	Peyman	424	434	3/24/97
	31	5,872,145	2/16/99	Placetka	514	415	8/14/97
	32	5,877,183	3/02/99	Cincotta	514	288	6/06/97

Examiner:

Date Considered:

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449
(Modified)U.S. Department of Commerce
Patent and Trademark Office

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(37 CFR § 1.98(b))

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Examiner Initials	Cite No.	Serial / Patent Number	Issue Date	Applicant / Patentee	Class	Subclass	Filing Date
	33	5,891,885	4/06/99	Caruso	514	289	10/24/96
	34	5,939,425	8/17/99	Caruso	514	289	5/19/97
	35	5,942,251	8/24/99	Merkus	424	493	4/17/98
	36	5,955,502	9/21/99	Hansen <i>et al.</i>	514	558	3/27/97
	37	6,010,719	1/04/00	Remon <i>et al.</i>	424	464	10/16/97
	38	6,043,244	3/28/00	Caruso	514	250	1/07/99
	39	6,077,539	6/20/00	Plachetka <i>et al.</i>	424	474	11/10/97
	40	6,103,218	8/15/00	Brucker <i>et al.</i>	424	45	4/23/97
	41	6,139,819	10/31/00	Unger <i>et al.</i>	424	9.52	10/17/97
	42	6,197,331	3/06/01	Lerner <i>et al.</i>	424	448	7/24/97
	43	6,200,604	3/13/01	Pather <i>et al.</i>	424	466	6/08/99
	44	6,221,392	4/24/01	Khankari <i>et al.</i>	424	464	12/16/99

FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS

		Document Number	Publication Date	Country / Patent Office	Class	Subclass	Translation	
							Yes	No
	45	00/16750	30.03.00	WIPO				
	46	0 324 725	12.01.89	EPO			X	

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

	47	Goodman and Gilman's "The Pharmaceutical Basis of Therapeutics", 8th ed., McGraw-Hill, Inc. (1990), pp. 944-947						
	48	Becker, "Migraine-associated symptoms: Clinical significance and management," <i>Can J Clin Pharmacol</i> 6 (Suppl A):15A-19A (1999)						
	49	Kiechel, "The Bioavailability and Kinetics of Dihydroergotamine" in Fitacha (Ed.); <i>Neuester Scand Der Dihydergot Forschung</i> . Sturtgart Georg Thiema: 32-46 (1984)						
	50	Migranal (dihydroergotamine mesylate, USP) Nasal Spray Information, Novartis Pharmaceuticals Company, Inc. Publication 30721901, 1997						
	51	D.H.E. 45 (dihydroergotamine mesylate) Injection, USP Information, Novartis Pharmaceuticals Company, Inc., Publication 30220906, 1998						
	52	Pharmaceutical Dosage Form: Tablets Vol. 1, 2nd Edition, Lieberman H. A. et al., Eds. Marcel Dekker, New York and Basel 1989. p. 354-356						
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Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.